

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN RE: GENERIC PHARMACEUTICALS  
PRICING ANTITRUST LITIGATION

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MDL 2724  
16-MD-2724  
HON. CYNTHIA M. RUFÉ

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IN RE: PROPRANOLOL CASES

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16-PP-27240

THIS DOCUMENT RELATES TO:

*ALL DIRECT PURCHASER ACTIONS*

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16-PP-27241

KPH HEALTHCARE SERVICES, INC.,  
a/k/a KINNEY DRUGS, INC., individually  
and on behalf of all others similarly situated

Civil Action No.

Plaintiffs,

v.

ACTAVIS ELIZABETH, LLC, TEVA  
PHARMACEUTICALS USA, INC.,  
PLIVA, INC., MYLAN, INC.,  
MYLAN PHARMACEUTICALS INC.,  
UDL LABORATORIES, INC., ENDO  
INTERNATIONAL PLC, PAR  
PHARMACEUTICAL HOLDINGS,  
HERITAGE PHARMACEUTICALS INC.,  
BRECKENRIDGE PHARMACEUTICALS,  
and UPSHER-SMITH LABORATORIES,

Jury Trial Demanded

Defendants.

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I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("Plaintiff"), brings this Class Action Complaint on behalf of itself and on behalf of a Class of direct

purchasers (hereinafter referred to as “Class Members”) who purchased generic Propranolol tablets and capsules from Defendants Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals Inc., UDL Laboratories, Inc., Endo International PLC, Par Pharmaceuticals Holdings, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceuticals, Inc., and Upsher-Smith Laboratories, Inc., during the period from December 18, 2013 to the present (“Class Period”).

2. Plaintiff seeks to recover damages incurred by itself and the Class due to Defendants’ and co-conspirators’ violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an overarching scheme to eliminate competition in the market for generic Propranolol and to artificially inflate prices through unlawful agreements.

3. As a result of Defendants’ anticompetitive scheme, Plaintiff and Class Members paid more for generic Propranolol than they otherwise would have paid in the absence of Defendants’ unlawful conduct. As set forth below, Defendants’ scheme violates the federal antitrust laws and, in particular, Section 1 of the Sherman Act, 15 U.S.C. § 1 (“Sherman Act”).

4. Plaintiff makes the allegations herein based on personal knowledge of these matters relating to itself and upon information and belief as to all other matters.

## **II. NATURE OF THE CASE**

5. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to foreclose competition in the market for generic Propranolol in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for the generic Propranolol.

6. Plaintiff, on behalf of itself and the proposed Class, seeks redress for the overcharge damages sustained as a result of Defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for generic Propranolol.

7. Plaintiff's allegations made on behalf of itself and Class Members are based on information made public by certain Defendants and from government investigations of alleged unlawful conduct in the generic drug market. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began an in-depth investigation of alleged criminal conduct related to pricing of generic drugs. As a result of the DOJ's investigation, grand jury subpoenas were issued to Defendants Actavis, Mylan, Par, and Heritage.

8. Generic Propranolol is one of the drugs at issue in the DOJ's ongoing investigation.

9. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing.<sup>1</sup> The NCPA's news release states,

Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

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<sup>1</sup> News release available at <http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say>.

“Over the last six months I have heard from so many of our members across the U.S. who have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate,” NCPA CEO B. Douglas Hoey, RPh, MBA wrote in a letter to the panels’ respective leaders, Chairman Tom Harkin (D-Iowa) and Ranking Member Lamar Alexander (R-Tenn.) and Chairman Fred Upton (R-Mich.) and Ranking Member Henry Waxman (D-Calif.).

10. NCPA’s survey of community pharmacists found the following:

- 77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.
- 86% of pharmacists said it took the pharmacy benefit manager (PBM) or other third-party payer between two and six months to update its reimbursement rate (but not retroactively).
- Patients may be referred to other pharmacies because the community pharmacy could not absorb losses of \$40, \$60, \$100 or more per prescription filled, due to inadequate and/or outdated reimbursement rates.
- 84% of pharmacists said the unsustainable losses per prescription are having a “very significant” impact on their ability to remain in business to continue serving patients.

11. In December 2016, the DOJ filed the first criminal indictments to result from the ongoing investigation of the generic drug industry.<sup>2</sup> On December 12 and December 13, 2016, the DOJ filed separate two-count felony indictments in the U.S. District Court for the Eastern District of Pennsylvania against two former executives of Defendant Heritage Pharmaceuticals, Inc. for conspiring to allocate customers and fix the prices of two other generic drugs, doxycycline hyclate and glyburide.

12. State Attorneys General are also conducting an ongoing investigation of the generic drug industry. On December 15, 2016, Connecticut Attorney General George Jepsen,

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<sup>2</sup> See *U.S. v. Glazer*, 2:16-cr-00506-RBS (E.D. Pa.) and *U.S. v. Malek*, 2:16-cr-00508-RBS (E.D. Pa.).

along with the Attorney Generals of nineteen other states, filed suit in the U.S. District Court for the District of Connecticut against Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Heritage Pharmaceuticals, Inc., Mayne Pharma (USA), Inc., Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc., for price-fixing of doxycycline hyclate delayed release and glyburide (“the AG Complaint”).<sup>3</sup> The AG Complaint states claims under Section 1 of the Sherman Act, 15 U.S. C. § 1, and notes that, “the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time.” Twenty additional states have since joined.

13. Plaintiff reserves the right to amend its complaint to include additional parties and claims related to the pricing of other generic drugs as new information from the government investigation becomes public.

### III. JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

15. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22 and 28 U.S.C. § 1391(b) and (c) because during the Class Period, the Defendants transacted business in the United States, including in this District.

16. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic Propranolol in the United States, including in this District. Defendants’ conduct had a direct,

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<sup>3</sup> See *Connecticut et al. v. Aurobindo Pharma USA, Inc. et al*, 3:16-cv-02056-VLB (D. Conn.).

substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

17. This Court has personal jurisdiction over each Defendant because, inter alia, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic Propranolol throughout the United States, including in this District; (c) had and maintained substantial contacts with the United States, including in this District; and/or (d) was engaged in an unlawful conspiracy to inflate the prices for generic Propranolol that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

#### **IV. THE PARTIES**

##### **A. PLAINTIFF**

18. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. (“KPH”) is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH directly purchased generic Propranolol from one or more Defendants during the Class Period. For example, KPH purchased generic Propranolol products from Defendants Breckenridge, Par, and Heritage. As a result of Defendants’ antitrust conspiracy, KPH paid supracompetitive prices for generic Propranolol and was injured by the illegal conduct alleged herein.

##### **B. DEFENDANTS**

19. Defendant Actavis Elizabeth, LLC (“Actavis”) is a Delaware limited liability company with its principal place of business at 200 Elmora Ave., Elizabeth, NJ 07207. At the

beginning of the Propranolol Capsules Class Period, Actavis was a subsidiary of Actavis, plc. In March 2015, Actavis, plc completed a merger with Allergan, plc (“Allergan”) and adopted Allergan’s name. In August 2016, Teva (defined below) purchased the Actavis Generics business, which included Defendant Actavis, from Allergan. During the Class Periods, Actavis sold Propranolol tablets and capsules in this District and throughout the United States.

20. Defendant Teva Pharmaceuticals USA, Inc. (“Teva Pharma”) is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, PA 19454. Teva Pharma’s parent corporation is Teva Pharmaceutical Industries, Ltd., an Israeli corporation with its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel. During the Class Periods, Teva Pharma sold Propranolol tablets and capsules in this District and throughout the United States.

21. Defendant Pliva, Inc. (“Pliva”) is a New Jersey corporation with its principal place of business at 72 Deforest Ave, East Hanover, NJ 07936. Pliva is a subsidiary of Teva Pharmaceutical Industries, Ltd. During the Class Periods, Pliva sold Propranolol tablets in this District and throughout the United States. Teva Pharma and Pliva will be referred to collectively as “Teva.”

22. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317. The parent corporation of Mylan Inc. is Mylan N.V., a Netherlands corporation with global headquarters in Hertfordshire, U.K., and in Canonsburg, Pennsylvania. During the Class Periods, Mylan Inc. sold Propranolol tablets and capsules in this District and throughout the United States through its subsidiaries, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.

23. Defendant Mylan Pharmaceuticals Inc. (“Mylan”) is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. During the Class Period, Mylan sold Propranolol in this District and throughout the United States.

24. Defendant UDL Laboratories, Inc. (“UDL”) is an Illinois corporation with its principal place of business at 1718 Northrock Ct, Rockford, IL 61103. UDL is, and was throughout the Class Period, a subsidiary of Mylan, Inc. During the Propranolol Tablets Class Period, UDL sold Propranolol tablets in this District and throughout the United States. Defendants Mylan Inc., Mylan Pharmaceuticals Inc. and UDL will be referred to collectively as “Mylan.”

25. Defendant Endo International PLC (“Endo International”) is an Irish corporation with its principal place of business located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland. During the Propranolol Tablets Class Period, Endo International’s subsidiary Qualitest Pharmaceuticals, Inc. sold Propranolol tablets in this District and throughout the United States.

26. Defendant Par Pharmaceuticals Holdings, Inc. (“Par”), is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chestnut Ridge, NY 10977. In September 2016, Endo International completed an acquisition of Par at which time it created a combined U.S. Generics segment that included Par and Qualitest, naming the segment Par Pharmaceutical, an Endo International Company. On information and belief, Qualitest merged into Par. Defendants Endo International, Par and Qualitest will be referred to collectively as “Endo.”



27. Defendant Heritage Pharmaceuticals Inc. (“Heritage”) is a Delaware corporation with its principal place of business at 12 Christopher Way #300, Eatontown, NJ 07724. During the Propranolol Tablets Class Period, Heritage sold Propranolol tablets in this District and throughout the United States. Heritage is a subsidiary of Emcure Pharmaceuticals Ltd., based in Pune, India.

28. Defendant Breckenridge Pharmaceuticals, Inc. (“Breckenridge”) is a Delaware corporation with its principal place of business at 1 Passaic Ave, Fairfield, NJ 07004. During the Propranolol Capsules Class Period, Breckenridge sold Propranolol capsules in this District and throughout the United States.

29. Defendant Upsher-Smith Laboratories, Inc. (“Upsher-Smith”) is a Minnesota corporation with its principal place of business at 6701 Evenstad Drive, Maple Grove, MN 55369. During the Propranolol Capsules Class Period, Upsher-Smith sold Propranolol capsules in this District and throughout the United States.

30. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants’ officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of Defendants’ business and affairs.

#### **V. UNIDENTIFIED CO-CONSPIRATORS**

31. Various other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted and performed acts and made statements in furtherance of the conspiracy.

32. The true names and capacities, whether individual, corporate, associate, or representative, is unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as

necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

33. At all relevant times, other persons, firms, and corporations, referred to herein as “co-conspirators,” the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful monopolization as described herein.

34. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

## **VI. FACTUAL ALLEGATIONS**

### **A. Overview of Generic Drug Market**

35. Generic drugs typically provide consumers with a lower-cost alternative to brand name drugs while providing the same treatment. Specifically,

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand name product.<sup>4</sup>

36. Further, “[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”<sup>5</sup>

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<sup>4</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G>

<sup>5</sup> *Id.*

37. Generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)).

38. Economic literature in the healthcare market has demonstrated that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand name drug rapidly loses sales, as much as 80% or more by the end of the first year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the corresponding generic accelerates as more generic options are available to purchasers.<sup>6</sup>

39. Generic competition usually enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and/or (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug

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<sup>6</sup> See, e.g., Ernst R. Berndt, et al., *Authorized Generic Drugs, Price Competition, And Consumers' Welfare*, Health Affairs 26, no. 3 (2007):790-799.

product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.

40. Drug companies that want to introduce a generic drug to the market file an Abbreviated New Drug Application (“ANDA”) with the FDA’s Center for Drug Evaluation and Research, Office of Generic Drugs. The filing is called “abbreviated” because the ANDA sponsor references data submitted in the approval of the Reference Listed Drug (“RLD”) (the brand name drug). “By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart.”<sup>7</sup> An ANDA sponsor is generally not required to include clinical trial data to establish the safety and efficacy of the drug. Instead, a generic drug company must show that its generic product is “bioequivalent” to the name brand drug,<sup>8</sup> i.e., the generic product and the brand RLD have the same (i) active ingredient, (ii) maximum amount of drug in the blood at a given time, (iii) total amount of drug in the blood over time, (iv) strength, dosage, dosage form, (v) expected safety and efficacy, and (vi) FDA approval of manufacturing facilities. Upon the FDA’s determination that bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

41. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code (“TE Code”).<sup>9</sup> An oral generic drug product will be coded “AB” if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine

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<sup>7</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD>.

<sup>8</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#A>.

<sup>9</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#T>.

whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations.<sup>10</sup>

**B. Consolidation in the Generic Drug Industry**

42. Since 2005, consolidations in the generic drug industry have affected control of product supply and pricing for consumers.

43. For example, Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation for \$7.4 billion in 2006; Barr Laboratories for \$7.4 billion in 2008; Ratiopharm, Germany's second largest generic drug producer, for \$5 billion in 2010, and agreed to acquire Allergan Generics in 2015 for \$40.5 billion. Watson Pharmaceuticals acquired Andrx Corporation in 2006 for \$1.9 billion; Daiichi Sankyo acquired a majority stake in Ranbaxy in 2008; and Endo Pharmaceuticals acquired Qualitest for \$1.2 billion in 2010.

44. In March 2015, Defendant Actavis merged with Allergan, and Defendant Teva acquired Actavis Generics in 2016. Defendant Endo acquired Qualitest Pharmaceuticals for \$1.2 billion in 2010, and Defendant Par in 2016. As a result of the consolidation, Defendants dominate the U.S. Propranolol market.

45. Consolidation in the generic drug industry has led to higher prices for consumers and the combining or discontinuation of generic product lines, which contributed to reducing price competition. Mergers within the generic drug industry were a reaction, in part, to the consolidation of distributors. Generic manufacturers then had leverage to charge higher prices if distributors were unable to negotiate lower prices with other generic manufacturers offering therapeutically equivalent drugs.

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<sup>10</sup> <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm>.

### C. Opportunities for Collusion

46. The DOJ is reportedly examining trade associations where Defendants allegedly have opportunities to communicate and collude, such as the Generic Pharmaceutical Association's ("GPhA"). According to an intelligence report from the *Policy and Regulatory Report* ("PaRR"), a source that was given inside information by someone with knowledge of the government's generic pricing investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."<sup>11</sup>

47. The GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.<sup>12</sup>

48. Defendants Teva and Par have representatives on GPhA's 2016 Board of Directors. An executive of Mylan N.V. was the 2016 GPhA Chair of the Board of Directors.

49. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition,

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<sup>11</sup> <http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07>.

<sup>12</sup> In February 2017, the GPhA changed its name to the Association for Accessible Medicines ("AAM"). See Russell Redman, *New name for Generic Pharmaceutical Association*, CHAIN DRUG REVIEW (Feb. 14, 2017), available at <http://www.chaindrugreview.com/new-name-for-generic-pharmaceutical-association/>.

GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections.”<sup>13</sup>

50. Generic drug manufacturers attend various industry trade shows throughout the year, including those hosted by the GPhA, National Association of Chain Drug Stores, Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.<sup>14</sup>

51. At these meetings and trade shows, generic drug manufacturers have opportunities to discuss and share competitively sensitive information, such as pricing, upcoming bids, and customer contracts.<sup>15</sup>

52. Many of these conferences and trade shows also include organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors.

53. High-level executives of generic drug manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic drug prices were increasing exponentially, at least thirteen (13) high-ranking male executives of various generic drug manufacturers met at a steakhouse in Bridgewater, New Jersey.<sup>16</sup>

54. Female sales representatives for generic drug manufacturers regularly hold meetings and dinners for “Girls Night Out” (“GNO”) and Women in the Industry events, where

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<sup>13</sup> <http://www.gphaonline.org/about/membership>.

<sup>14</sup> See AG Complaint at ¶ 50.

<sup>15</sup> *Id.* at ¶ 51.

<sup>16</sup> *Id.* at ¶ 55.

competitively sensitive information is discussed.<sup>17</sup> For example, GNOs were held at the ECRM conference in February 2015, in Baltimore in May 2015, and at the NACDS conference in August 2015.<sup>18</sup>

55. Many generic drug manufacturers, including two of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, providing them with more opportunities to meet and collude.

#### **D. Generic Propranolol Market and Pricing Information**

56. Propranolol is a beta-blocker used to treat tremors, angina, hypertension, heart rhythm disorders, and other heart and circulatory conditions. Propranolol is also used to treat or prevent heart attacks and to reduce the severity and frequency of migraine headaches. Propranolol was first discovered in 1964 and is on the World Health Organization's ("WHO") List of Essential Medicines. Propranolol is the generic version of Inderal. The U.S. Food and Drug Administration approved Inderal, developed by Wyeth Pharmaceuticals, Inc., in 1967.

57. Defendants each attended the GPhA Fall Technical Conference in Bethesda, Maryland on October 28-30, 2013.

58. These meetings provided Defendants with opportunities to collude, along with Defendants' other contacts. On information and belief, Defendants agreed to increase pricing for Propranolol at these meetings.

59. Defendants Mylan, Actavis, Breckenridge, and Upsher-Smith sold Propranolol capsules during the Propranolol Capsules Class Period. Prior to October 2013, the average amount in the U.S. paid for Propranolol capsules was stable. Within a few weeks of the October

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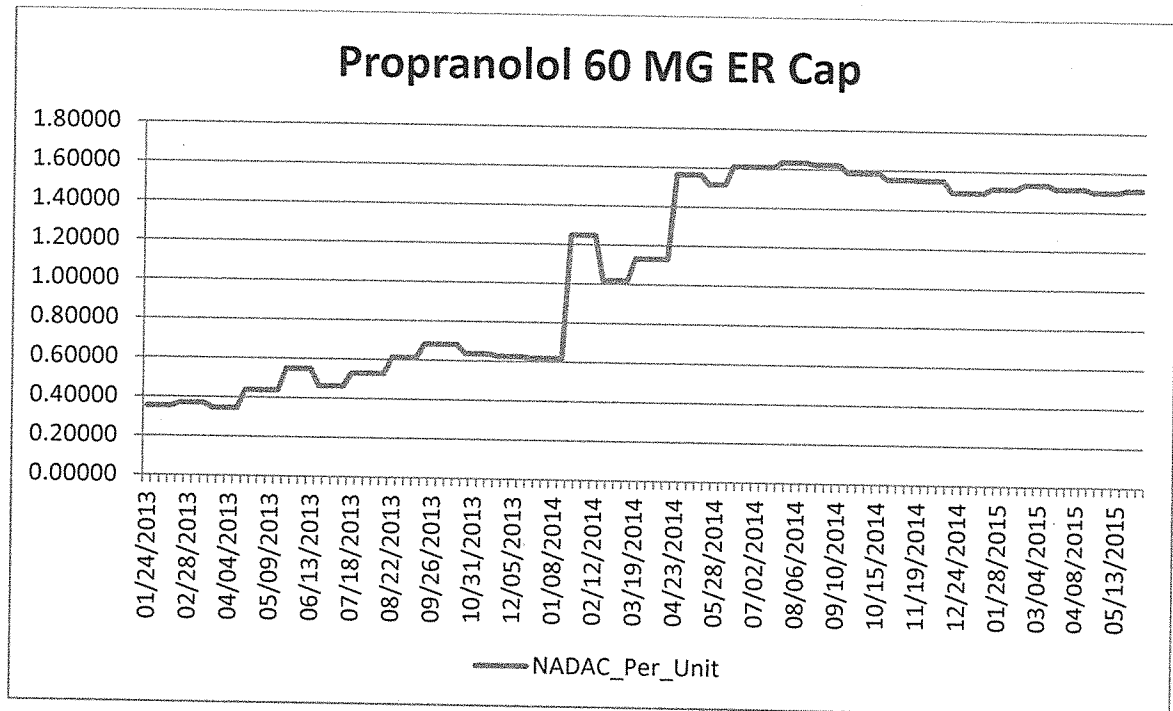
<sup>17</sup> *Id.* at ¶ 57.

<sup>18</sup> *Id.* at ¶ 60.

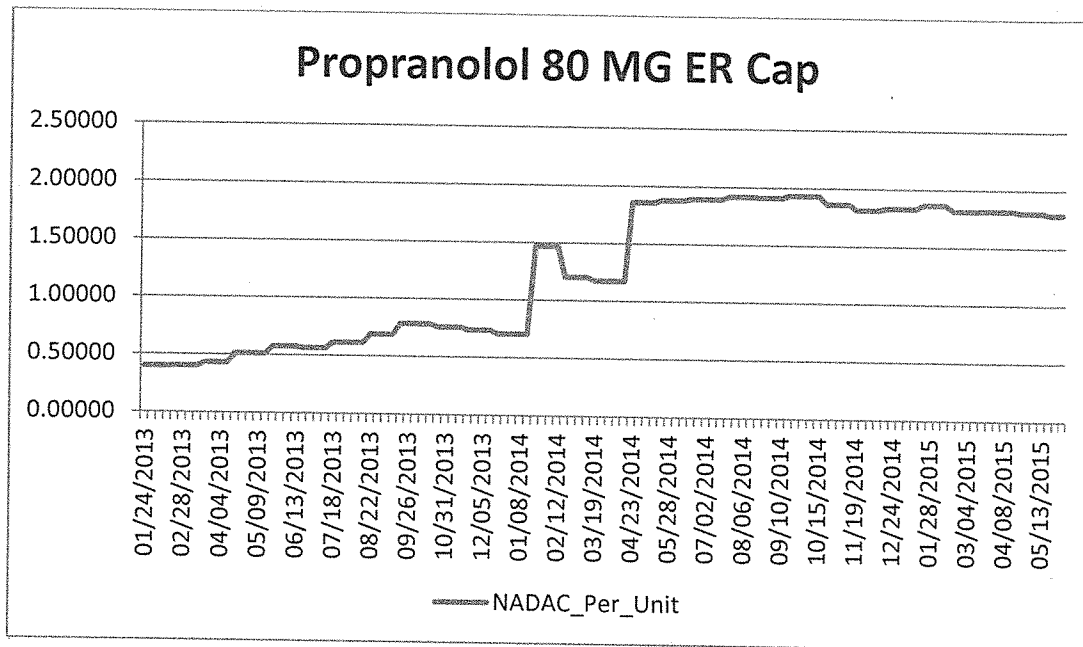


2013 GPhA meeting, the average prices for Propranolol capsules began to increase by extraordinary amounts:

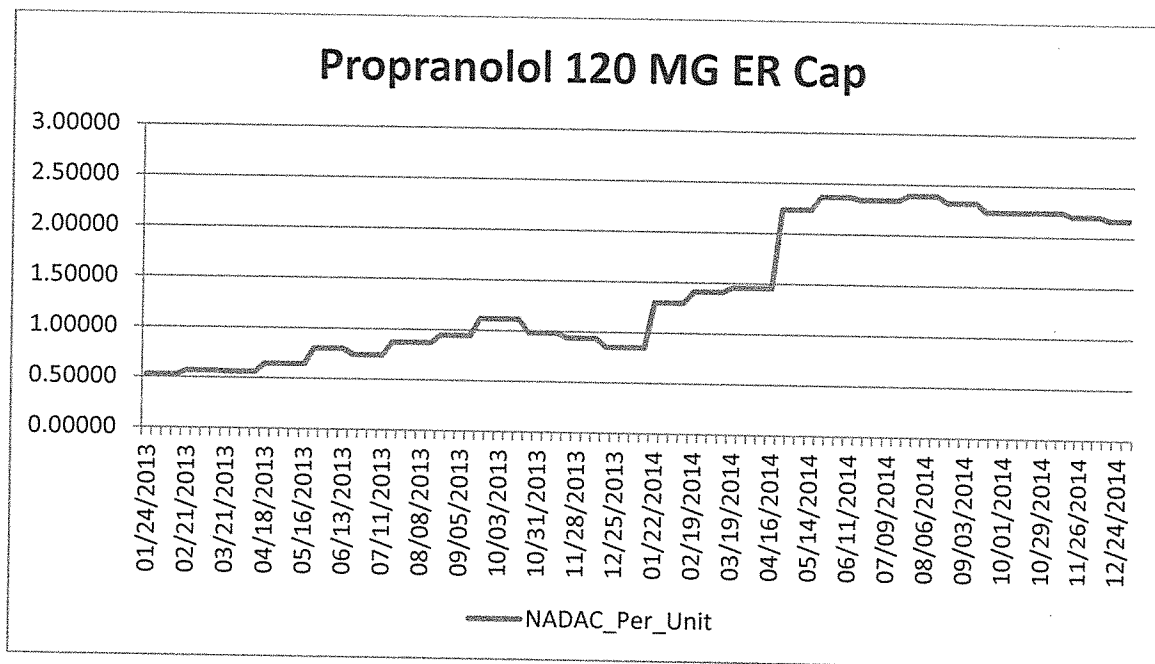
- a. **Propranolol 60mg ER Capsules:** Between December 18, 2013 and July 23, 2014, average prices increased by 164%.



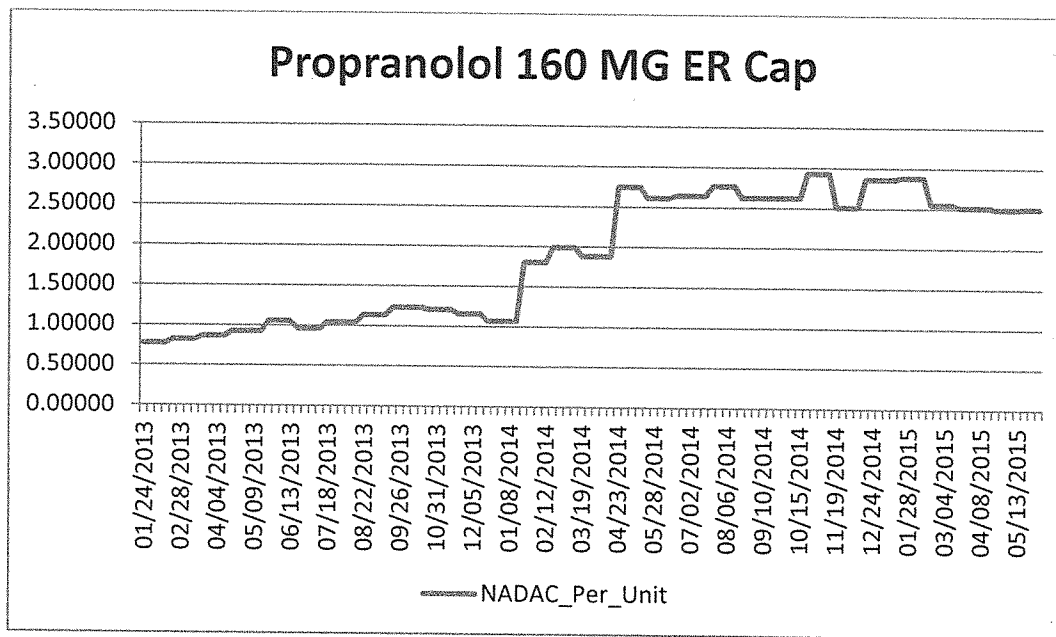
- b. **Propranolol 80mg ER Capsules:** Between December 18, 2013 and September 17, 2014, average prices increased by 174%.



- c. **Propranolol 120mg ER Capsules:** Between December 18, 2013 and July 23, 2014, average prices increased by 181%.



- d. **Propranolol 160mg ER Capsules:** Between December 18, 2013 and October 22, 2014, average prices increased by 174%.

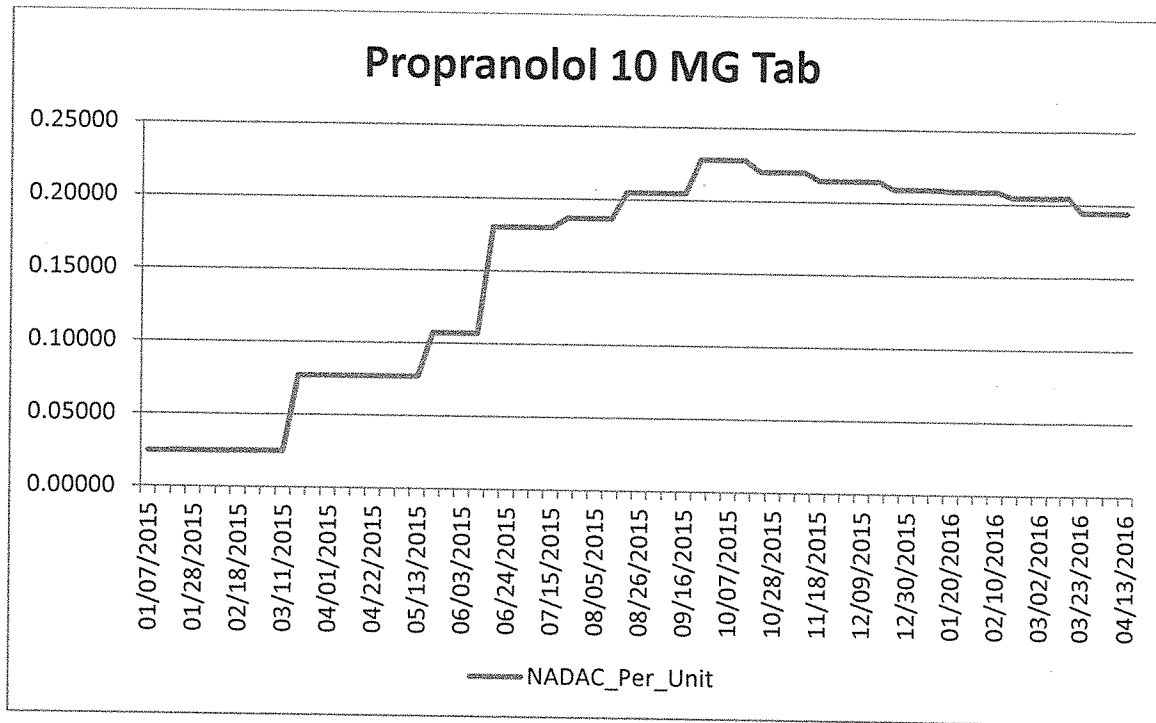


60. Defendants' price increases were, for the most part, in lockstep. Prices for Propranolol capsules remained at supra-competitive levels throughout the Class Period.

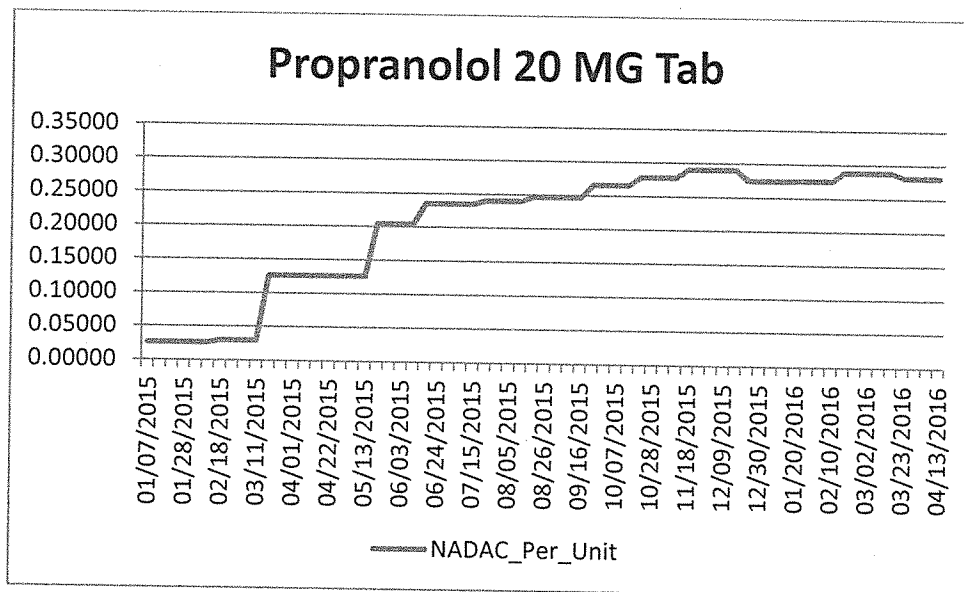
61. Beginning in February 2015, contrary to past practice, Defendants caused the price of Propranolol tablets to dramatically increase in unison. The increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Propranolol capsules in the United States. The agreement was furthered by discussions held at GPhA meetings, including a meeting in Miami Beach, Florida in February 2015 that was attended by Defendants.

62. Defendants Mylan, Actavis, Teva, Endo, and Heritage sold Propranolol tablets during the Propranolol Tablets Class Period. Prior to February 2015, the average amount in the U.S. paid for Propranolol tablets was stable. Within a few weeks of the February 2015 meeting, the average prices for Propranolol tablets began to increase by extraordinary amounts:

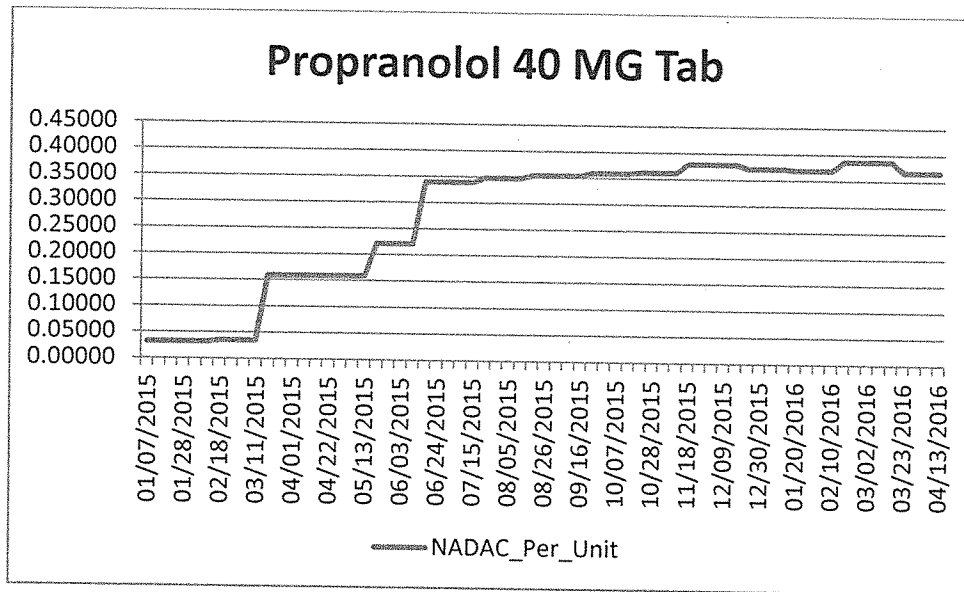
- a. **Propranolol 10mg Tablets:** Between March 18, 2015 and September 23, 2015, average prices increased 819%.



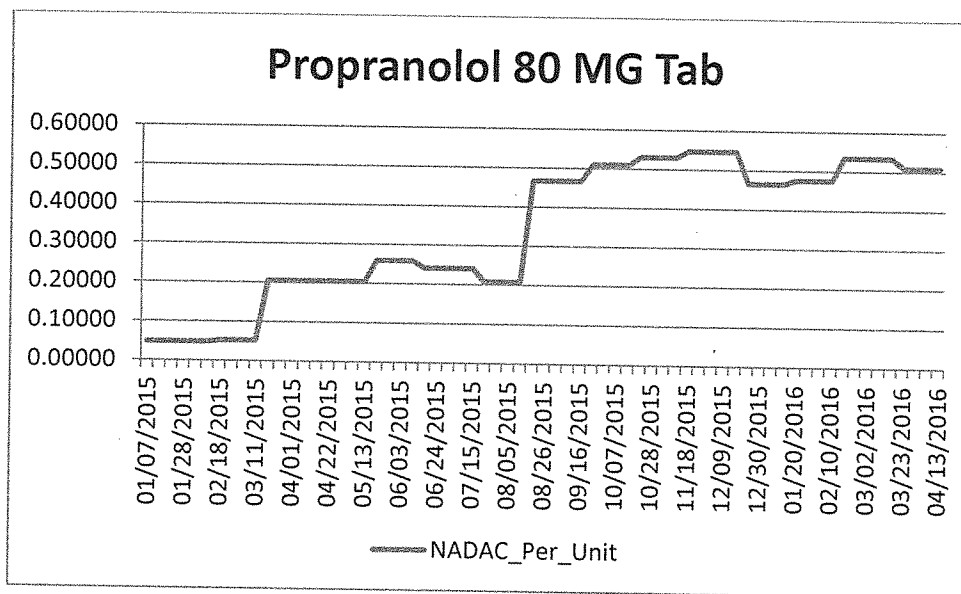
- b. **Propranolol 20mg Tablets:** Between March 11, 2015 and November 18, 2015, average prices increased 892%.



- c. **Propranolol 40mg Tablets:** Between February 18, 2015 and February 17, 2016, average prices increased 1008%.



d. **Propranolol 80mg Tablets:** Between February 11, 2015 and November 18, 2015, average prices increased 1033%.



63. Defendants' price increases were, for the most part, in lockstep. Prices for Propranolol tablets remained at supra-competitive levels throughout the Class Period.

64. There were no reasonable justifications for this abrupt shift in pricing, as Defendants' price increases were not necessitated by increased manufacturing costs, or research and development costs. Likewise, there were no shortages of Propranolol in the United States.

65. Federal law requires drug manufacturers to report potential drug shortages to the FDA, the reasons for the shortage, and the expected duration of the shortage. No supply disruption was reported by Defendants with respect to Propranolol during the Class Periods.

66. At all times during the class period, there were at least three or more separate manufacturers of generic Propranolol. The active ingredient for the drug product, Propranolol hydrochloride, has four approved holders of active Drug Master Files (“DMF”).<sup>19</sup>

67. Drug shortage reports for the time period do not list Propranolol as being in short supply.<sup>20</sup>

68. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as shown in the tables, absent anticompetitive conduct.

69. In a report dated April 21, 2015, Richard Evans, Scott Hinds and Ryan Baum at Sector & Sovereign Research concluded that: “A plausible explanation is that generic manufacturers . . . **are cooperating to raise the prices of products whose characteristics** (low sales due to either very low prices or very low volumes) accommodate price inflation.” (Emphasis added).

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<sup>19</sup> A Drug Master File, or DMF, is a regulatory document that contains the complete information for an active pharmaceutical ingredient (or API or drug substance), or a finished dosage form (the complete drug product, such as a tablet). The DMF contains information on the drug manufacture, stability, purity, chemistry, packaging and the good manufacturing practices that were used in the processes to make the product that is the subject of the DMF.

<sup>20</sup> See FDA Drug Shortages website, <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm#P>; American Society of Health-System Pharmacists, <http://www.ashp.org/shortages>.

70. Consumers have suffered harm due to the supracompetitive prices of Propranolol. As noted in letters from members of Congress to generic drug manufacturers as part of a wide investigation into unexplained increases in generic drug prices:

This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country “have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate” and “77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.” These price increases have a direct impact on patients’ ability to purchase their needed medications. The NCPA survey found that “pharmacists reported patients declining their medication due to increased co-pays,” and “84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a ‘very significant’ impact on their ability to remain in business to continue serving patients.

71. Supracompetitive generic drug prices also have a detrimental impact on direct purchasers of the drugs:

One factor that squeezed retailers’ profit margins was the generic price inflation that roiled the pharmacy market, beginning in 2013 and extending through 2014 into 2015. The sharp price hikes — particularly for single-source generics — increased pressure on pharmacy retailers, who were caught between rising acquisition costs and limits on how much they could raise their own prices at the pharmacy counter. Compounding the squeeze: the frequent failure of MAC (maximum allowable cost)- and AMP (average manufacturer price)- based drug pricing models — and the payers that base their pharmacy reimbursements on them — to keep pace with the inflationary price spiral for some generics in their reimbursements to pharmacies for the medicines dispensed to their members.<sup>21</sup>

72. Similarly, a 2015 white paper published by Elsevier Clinical Solutions noted:

High generic drug prices have had an adverse effect on almost everyone in the pharmaceutical supply chain. Consumers face higher co-pays and prices and health plans are dealing with higher drug spend. Physicians are finding the need to prescribe alternative drug therapies while dealing with angry patients. In some cases, consumers are declining their medications due to increased prices. Many pharmacies are receiving inadequate reimbursements and can lose money when

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<sup>21</sup> Drug Store News, “Generic Drug Report 2016,” available at [https://www.drugstorenews.com/sites/drugstorenews.Com/files/GenericReport\\_2016.pdf](https://www.drugstorenews.com/sites/drugstorenews.Com/files/GenericReport_2016.pdf).



drugs must be purchased at rapidly rising prices but reimbursed at lower predetermined rates.<sup>22</sup>

73. Defendants' adherence to their price-fixing scheme generated considerable profits. For example, in Endo's Q1 2015 earnings call on May 11, 2015, Endo CEO Rajiv De Silva stated "[i]n 2015, we expect strong double-digit revenue growth for U.S. Generics, as a result of consistent volume growth supplemented by recent pricing opportunities...."

74. Currently, the price of Propranolol continues to be supracompetitive.

#### **E. Government Investigations of Generic Drug Industry**

75. As noted above, defendants' conduct in generic pharmaceutical pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as state government investigations.

76. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to fourteen pharmaceutical manufacturers, including Defendants Actavis, Endo, Heritage, Mylan and Teva, seeking information relating to the escalating prices of generic pharmaceuticals (the "October Letters").

77. The October Letters were accompanied by a press release by Senator Sanders and Congressman Cummings, which stated,

"We are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening illnesses," Sanders, chairman of a Senate health care subcommittee, and Cummings, ranking member of the House oversight committee, wrote in letters to 14 pharmaceutical companies.

...

Cummings and Sanders cited a survey that found pharmacies across the country "have seen huge upswings in generic drug prices that are hurting patients" and

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<sup>22</sup> "The Impact of Rising Generic Drug Prices on the U.S. Drug Supply Chain," at pp. 1-2, available at [http://www.ncpa.co/pdf/elsevier\\_wp\\_genericdrug.pdf](http://www.ncpa.co/pdf/elsevier_wp_genericdrug.pdf).



having a “very significant” impact on pharmacists’ ability to continue serving patients. The study for the National Community Pharmacists Association also found some patients refused to fill needed prescriptions because of rising prices.

“It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs. Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We’ve got to get to the bottom of these enormous price increases,” Sanders said.

“When you see how much the prices of these drugs have increased just over the past year, it’s staggering, and we want to know why,” said Cummings. “I am very pleased that Chairman Sanders has joined me in this bicameral investigation because in some cases these outrageous price hikes are preventing patients from getting the drugs they need.”<sup>23</sup>

78. The U.S. Senate HELP Committee held a Senate Hearing on November 20, 2014 (*Why Are Some Generic Drugs Skyrocketing in Price?*).

79. During the Senate Hearing on generic pharmaceutical prices, pharmacist Rob Frankil testified on November 20, 2014 that, “it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs.”<sup>24</sup>

80. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter to the Office of the Inspector General (“OIG”) of the Department of Health and Human Services asking that the OIG “examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs.”<sup>25</sup> The OIG responded to the request on April 13, 2015 and stated that it

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<sup>23</sup> Press release, Congress Investigating Why Generic Drug Prices are Skyrocketing, Oct. 2, 2014, available at <http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing>.

<sup>24</sup> Testimony of Rob Frankil, U.S. Senate Hearing, *Why Are Some Generic Drugs Skyrocketing in Price?* (Nov. 20, 2014), available at <http://www.help.senate.gov/imo/media/doc/Frankil.pdf>.

<sup>25</sup> <http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file>.

planned to review quarterly average manufacturer prices [“AMPs”] for the top 200 generic drugs from 2005 through 2014, and would “determine the extent to which the quarterly AMPs exceeded the specified inflation factor.”<sup>26</sup> The OIG concluded that escalating generic drug prices have cost taxpayers \$1.4 billion in overpayment by Medicaid.<sup>27</sup> In a 2015 budget deal by Congress, legislation requires generic drug manufacturers to pay back the Medicaid program when their prices rise faster than inflation. Later in 2015, Senator Sanders and Representative Cummings proposed comprehensive legislation to address prescription drugs prices.

81. Subsequent congressional hearings concerning the dramatic rise of generic pharmaceutical prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging’s December 9, 2015 hearing, Erin D. Fox, the Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that “[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage.”

82. According to a June 26, 2015 report by the service Policy and Regulatory Report (“PaRR Report”) (available at <http://www.mergermarket.com/pdf/DoJCollusion-Generic-Drug-Prices-2015.pdf>):

A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the

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<sup>26</sup> <http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file>.

<sup>27</sup> Office of the Inspector General, Average Manufacture Prices increased faster than Inflation for Many Generic Drugs, December 2015, available at <https://oig.hhs.gov/oas/reports/region6/61500030.pdf>.

department's largest criminal antitrust probe ever. Like in that case, prosecutors expect "to move from one drug to another in a similar cascading fashion."

83. The DOJ is conducting an ongoing investigation into generic drug pricing. Several leading generic drug manufacturers have been subpoenaed for information, documents and testimony relating to "communication or correspondence with any competitor in the sale of generic prescription medications."<sup>28</sup> Grand jury subpoenas have been issued to, among other generic pharmaceutical companies, Actavis, Mylan, Endo, Teva and Heritage.

84. Mylan N.V., parent company to Mylan Pharmaceuticals, Inc., reported on February 16, 2016 in its 10-K that, "[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company's generic products and communications with competitors about such products."

85. Par's 10-K dated March 12, 2015 disclosed that it had received a subpoena from the Antitrust Division of the DOJ requesting documents related to communications with competitors regarding another generic medication, digoxin.

86. Par's parent company, Endo, stated in a 10-Q for the third quarter of 2015 that it also had received a subpoena for information focused primarily on pricing for Par's generic digoxin and doxycycline products.

87. On June 21, 2016, Teva received a subpoena from the DOJ seeking documents and other information relating to the marketing and pricing of certain of Teva's generic products and communications with competitors about such products. Defendant Actavis received a similar subpoena in June 2015.

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<sup>28</sup> See Impax Laboratories, Inc., Form 8-K, November 3, 2014.

88. On July 12, 2016, Teva received a subpoena from the Connecticut AG seeking documents and other information relating to potential state antitrust law violations. Defendant Actavis has also received a similar subpoena from the Connecticut AG.

89. Mylan N.V., parent company to Mylan Pharmaceuticals, Inc., reported on February 16, 2016 in its 10-K that, “[o]n December 21, 2015, the Company received a subpoena and interrogatories from the Connecticut Office of the Attorney General seeking information relating to the marketing, pricing and sale of certain of the Company’s generic products and communications with competitors about such products.”

90. On October 7, 2016, Mylan disclosed in a filing with the SEC that on September 8, 2016, the DOJ “subpoenaed a company subsidiary, a senior executive and other employees about alleged price fixing and also executed multiple search warrants related to its probe.” Mylan further disclosed that the DOJ is seeking “additional information relating to the marketing, pricing and sale of” several generic drugs, including Propranolol, “and any communications with competitors about such products.”

91. In December 2015, Defendant Endo received Interrogatories and Subpoenas Duces Tecum from the Connecticut AG requesting information regarding pricing of certain of its generic products.

92. As discussed above, the first indictments to result from the DOJ’s investigation of the generic drug industry were filed in the Eastern District of Pennsylvania in December 2016 against former executives of Heritage Pharmaceuticals, Inc., Jeffrey A. Glazer and Jason T. Malek. Glazer and Malek pleaded guilty to violating Section 1 of the Sherman Act in January 2017.

93. Further, as a result of the Connecticut Attorney General’s two-year investigation of the generic drug industry, the AG Complaint was filed in December 2016 and provides additional details on anticompetitive conduct in certain generic drug markets. According to the AG Complaint, “[i]n July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that investigation, which is still ongoing, uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States.

94. The fact that grand jury subpoenas were served on defendants is indicative that they have potentially violated antitrust law. According to the DOJ’s *Antitrust Division Manual*, “staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution.”<sup>29</sup> If a grand jury request memorandum is approved by the DOJ field office chief, “a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division].”<sup>30</sup> “The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation.”<sup>31</sup> Then, “[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the

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<sup>29</sup> See Antitrust Division Manual, Chapter III, Section F.1 at III-82 (Apr. 2015), available at <https://www.justice.gov/atr/division-manual>.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at III-83.

offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred.”<sup>32</sup>

95. The AG Complaint provided information as to how certain Defendants allegedly carry out their anticompetitive schemes.

96. For example, when entering a generic drug market, Heritage, Teva and Mylan and others routinely sought out their competitors in an effort to reach agreement to allocate market share, maintain high prices and/or avoid competing on price. These agreements had the effect of artificially maintaining high prices for a large number of generic drugs and creating an appearance of competition when in fact none existed.

97. In 2013 and 2014, Malek, former President of Defendant Heritage, and Glazer, former CEO and Chairman of Defendant Heritage, compiled a large list of generic drugs and instructed employees to contact competitors to reach agreement to increase prices and allocate customers. Malek was responsible for contacting Defendants Teva and Mylan and did so with respect to a number of drugs, including, on information and belief, Propranolol. The employees also contacted competitors and reached agreements to raise prices.

98. During the course of these communications, Heritage, Teva and Mylan executives agreed to raise prices, allocate market share and refrain from competing with one another for customers. The objective was to avoid a price war which would reduce profitability for Defendants. Mylan agreed to "walk away" from at least one large national wholesaler and one large pharmacy chain to allow Heritage to obtain the business and increase its market share.

99. In addition to reaching agreements with competitors to allocate markets for a number of different generic drugs, including, on information and belief, Propranolol, Heritage,

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<sup>32</sup> *Id.*

Mylan, Teva and others routinely and as part of their regular course of business, sought and obtained agreements with competitors to fix and raise prices.

100. Malek was responsible for communicating with Defendant Teva, among others, which was a competitor on several of the drugs on the list, including, on information and belief, Propranolol. Malek had a direct relationship with a Teva executive and was able to successfully communicate with her and reach an agreement to raise prices on several drugs, including, on information and belief, Propranolol.

101. Both Malek and Glazer pushed Heritage employees to communicate with their competitors and obtain agreements to raise prices.

102. In 2014, a Teva executive met in person and discussed the price increase strategies with a number of different competitors at the Minnesota Multistate Contracting Alliance for Pharmacy (“MMCAP”) conference. According to its website, MMCAP is a “free, voluntary group purchasing organization for government facilities that provide healthcare services. MMCAP has been delivering pharmacy and healthcare value to members since 1985. MMCAP’s membership extends across nearly every state in the nation, delivering volume buying power. Members receive access to a full range of pharmaceuticals and other healthcare products and services; such as, medical supplies, influenza vaccine, dental supplies, drug testing, wholesaler invoice auditing and returned goods processing.”

103. One of the targets of the DOJ investigation has reportedly applied for leniency. This is significant because the applicant must admit to participation in a criminal antitrust violation. As the DOJ notes on its web site:

5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?



Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.<sup>33</sup>

104. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials."<sup>34</sup>

105. DOJ and state government investigations of Defendants' alleged price-fixing conduct in the generic pharmaceutical industry continue.

#### **F. Order Denying Motion to Dismiss in *Propranolol* Antitrust Litigation**

106. In a previous Propranolol price-fixing case, *In re: Propranolol Antitrust Litigation*, the U.S. District Court for the Southern District of New York entered an Opinion and Order on April 6, 2017 denying a motion to dismiss direct purchasers' consolidated amended complaint. *See In re Propranolol Antitrust Litig.*, No. 16-cv-9901, -- F.3d --, 2017 WL 1287515 (S.D.N.Y. Apr. 6, 2017) (Rakoff, J.) ("Propranolol Order").<sup>35</sup> Plaintiffs in the *Propranolol* case

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<sup>33</sup> Frequently Asked Questions Regarding the Antitrust Division's Leniency Program, Dept. of Justice (last visited Jan. 24, 2017), *available at* <http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program>

<sup>34</sup> *Id.*

<sup>35</sup> The *Propranolol* defendants are the same as those named herein: Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Par Pharmaceutical, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceutical, Inc., and Upsher-Smith Laboratories, Inc.



alleged a conspiracy among generic manufacturers to manipulate the market for generic propranolol.

107. In denying the defendants' motion to dismiss, Judge Rakoff found that *Propranolol* plaintiffs pled a plausible price-fixing conspiracy and that plaintiffs alleged market specific factors suggesting that defendants had an incentive to manipulate prices. *See* Propranolol Order at 11, 13, 24. Judge Rakoff noted that Plaintiffs' pleadings "set forth in detail a regulatory regime that has historically pushed the price of Propranolol downwards and gradually reduced defendants' profits, thereby giving them a common motive to conspire." *Id.* at 13. Further, Judge Rakoff found that plaintiffs' pleadings "allege a pattern of price fixing spanning several years and no clear mechanism through which the defendants could legitimately and consistently monitor each other's pricing activity." *Id.* at 15-16.

108. The *Propranolol* plaintiffs alleged the presence of four plus factors to plausibly establish that the defendants conspired to fix prices of Propranolol capsules and tablets in 2013 and 2015: "(1) defendants had a motive to increase prices because they operate in an oligopolistic market characterized by falling prices; (2) the price increases were against defendants' self-interest because in a competitive market, defendants should have tried to undercut each other's prices to increase their market share; (3) defendants frequently communicated at trade association meetings; and (4) there are ongoing state and federal investigations for price manipulation of generic drugs, including Propranolol." *Id.* at 10-11, 24.

109. Judge Rakoff rejected defendants' explanations for Propranolol price increases. For example, "plaintiffs plausibly allege that because the FDA did not report a shortage of Propranolol capsules following Mylan's exit, there was no 'shift' in the total supply of Propranolol that would rationally increase prices." *Id.* at 17. In addition, "while it is true that

defendants' price increases did not always align on a monthly basis, defendants consistently raised prices on a bi-monthly and quarterly basis, which is consistent with an illegal agreement." *Id.* (emphasis in original). The same price increases are alleged in the instant complaint.

**G. *In re: Generic Pharmaceuticals Pricing Antitrust Litigation***

110. On April 6, 2017, the U.S. Judicial Panel on Multidistrict Litigation entered a Transfer Order granting Rochester Drug Cooperative, Inc.'s motion to transfer ten generic drug price-fixing actions to the Eastern District of Pennsylvania for inclusion in *In re: Generic Digoxin and Doxycycline Antitrust Litigation*, MDL No. 2724 (E.D. Pa.). The MDL was renamed *In re: Generic Pharmaceuticals Pricing Antitrust Litigation* and now includes price-fixing allegations for eighteen generic drugs: (1) Doxycycline, (2) Digoxin, (3) Albuterol, (4) Clomipramine, (5) Desonide, (6) Pravastatin, (7) Divalproex, (8) Benazepril HCTZ, (9) Levothyroxine, (10) Propranolol, (11) Baclofen, (12) Glyburide, (13) Ursodiol, (14) Amitriptyline, (15) Lidocaine/Prilocaine, (16) Clobetasol, (17) Fluocinonide, and (18) Econazole.

111. This case has been filed as a related case to *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, MDL No. 2724.

**VII. THE PROPRANOLOL MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION**

112. The factors necessary to show that a market is susceptible to collusion are present in this case:

- (1) **High Degree of Industry Concentration** – A concentrated market is more susceptible to collusion and other anticompetitive practices. The Propranolol market is highly concentrated and is dominated by a handful of companies. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.

- (2) **Barriers to Entry** – Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. For example, while ANDAs are generally approved faster than NDAs, they may still take longer than a year to obtain approval and a majority of ANDAs are rejected. Barriers to entry increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supra-competitive prices. As the dominant players in the Propranolol market, Defendants were able to fix, raise, and maintain their prices for Propranolol without competitive threats from rival generic drug manufacturers.
- (3) **Demand Inelasticity** – Generic Propranolol is necessary treatment for millions of patients. If a price change triggers a smaller proportionate change in quantity of the drug demanded, then the demand for the drug is said to be inelastic. If demand is inelastic, price increases result in limited declines in quantity sold or consumed in the market. For a cartel to profit from supracompetitive prices, demand must be inelastic at competitive prices such that cartel members are able to raise prices without triggering a decline in demand that would make a concerted price increase unprofitable. Demand for Propranolol is highly inelastic because it is a unique product for which there is no reasonable substitute. Propranolol is a necessary treatment for millions of patients for which no substitutes are available. Propranolol is thus particularly susceptible to collusive price fixing as price increases will not result in such a loss of sales as to reduce profits, but instead will result in more profits for cartel members.
- (4) **Lack of Substitutes** – Patients are often unable to substitute other medications for generic Propranolol. As noted above, Propranolol is on the WHO's List of Essential Medicines.
- (5) **High Degree of Interchangeability** – Propranolol is a commodity product. Defendants' generic Propranolol products are interchangeable as they contain the same chemical compounds made from the same raw materials and are therapeutically equivalent. Thus, generic Propranolol is standardized across suppliers and is highly interchangeable from one Defendant to the next. This characteristic facilitates collusion because cartel members can more easily monitor and detect deviations from a price-fixing agreement. In addition, because these are commodity products, all Defendants had to raise prices for the cartel to work. Indeed, it was against a Defendant's individual economic interest to raise prices since the other Defendants could have priced below that Defendant's price and taken substantial market share.
- (6) **Opportunities for Contact and Communication Among Competitors** – Defendants are members of the trade association GPhA, and attend other industry events and meetings, which provide opportunities to communicate. Defendants' representatives regularly attended meetings of GPhA, including the October 2013 and February 2015 meetings, and meetings of other trade associations during the Class Periods. Indeed, the DOJ is reportedly analyzing trade associations like GPhA as a potential avenue for facilitating collusion between different generic drug

manufacturers as part of its years-long investigation into anticompetitive pricing activities among them.

113. Defendants' dominant market power has allowed them to substantially foreclose the market to rival competition, thereby impairing competition, maintaining and enhancing market power, and enabling Defendants to charge Plaintiff and the Class Members inflated prices above competitive levels for generic Propranolol.

114. Propranolol is a commodity product. Therefore, absent a cartel, if any manufacturer increased the price of Propranolol, it would be expected that its competitors would not increase the price but would seek to sell more Propranolol to the first manufacturer's customers. Accordingly, it would not be in any manufacturer's unilateral self-interest to increase the price of the Propranolol it sold unless it had an agreement with the other manufacturers that they would do the same.

115. During the Class Period, there was no significant increase in the costs of making Propranolol and no significant increase in demand. Nonetheless, there were extraordinary increases by each of the Defendants in the prices they charged their customers for Propranolol. Such price increases in a commodity product for which there were no significant increases in costs or demand would not have been in each Defendant's unilateral self-interest absent the existence of a cartel.

### **VIII. CLASS ACTION ALLEGATIONS**

116. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf the following Classes:

- a. All persons or entities that directly purchased Propranolol capsules from Defendants in the United States and its territories and possessions at any time during the Propranolol Capsules Class Period (December 18, 2013 to the present). Excluded from the Class are Defendants and their officers, directors, management,

employees, subsidiaries, or affiliates, and all federal governmental entities; and

- b. All persons or entities that directly purchased Propranolol tablets from Defendants in the United States and its territories and possessions at any time during the Propranolol Tablets Class Period (February 18, 2015 to the present). Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

117. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds of members of the Classes, geographically dispersed throughout the United States such that joinder of all members of the Classes is impracticable. Further, the Classes are readily identifiable from information and records maintained by Defendants

118. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff's interests are not antagonistic to the claims of the other Members of the Classes, and there are no material conflicts with any other member of the Classes that would make class certification inappropriate. Plaintiff and all members of the Classes were damaged by the same wrongful conduct of Defendants.

119. Plaintiff will fairly and adequately protect and represent the interests of the Classes. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Classes.

120. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.

121. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to the entire Classes, thereby determining damages with

respect to the Classes as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

122. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, include, but are not limited to, the following:

- (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of Propranolol capsules and tablets in the United States;
- (b) The duration and extent of the alleged contract, combination, or conspiracy;
- (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
- (d) The effect of the contract, combination, or conspiracy on the prices of Propranolol capsules and tablets in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for Propranolol capsules and tablets;
- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Classes; and
- (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

123. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

124. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

### **IX. INTERSTATE TRADE AND COMMERCE**

125. Defendants are the leading manufacturers and suppliers of Propranolol sold in the United States.

126. Propranolol is produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

127. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Propranolol throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

128. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

129. Defendants' and their co-conspirators' conduct, including the marketing and sale of Propranolol, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

130. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Propranolol within the United States.

131. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Propranolol, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Propranolol prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.



**X. DEFENDANTS' ANTITRUST VIOLATIONS**

132. Defendants' combination and conspiracy had the following anticompetitive effects in the market for generic Propranolol:

- (a) Competition in the market for generic Propranolol has been reduced;
- (b) Prices for generic Propranolol have increased and have not followed the typical pricing patterns of generic drugs over time; and
- (c) U.S. purchasers have been deprived of the benefit of price competition in the market for generic Propranolol.

133. During the Class Period, Plaintiff and members of the Classes directly purchased generic Propranolol from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and members of the Classes paid more for generic Propranolol than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

134. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff and members of the Classes have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

135. Defendants' misconduct reduced competition in the generic Propranolol market, reduced choice for purchasers, and caused injury to purchasers.

136. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic Propranolol.

**XI. CLAIM FOR RELIEF**

**VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1**



137. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

138. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

139. Defendants' anticompetitive acts were intentional, were directed at the sales of Propranolol in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Propranolol prices throughout the United States.

140. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:

- c. Prices charged to, and paid by, Plaintiff for Propranolol were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
- d. Plaintiff was deprived of the benefits of free, open, and unrestricted competition in the sale of Propranolol in the United States market; and
- e. Competition in establishing the prices paid for Propranolol was unlawfully restrained, suppressed, or eliminated.

141. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

142. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of generic Propranolol in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

143. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

144. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic Propranolol, as described herein.

145. Defendants' and their co-conspirators' anticompetitive activities directly and proximately caused injury to Plaintiff in the United States. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff paid artificially inflated prices for Propranolol.

146. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic Propranolol than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

147. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

## **XII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires them to take affirmative steps to dissipate the effects of the violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

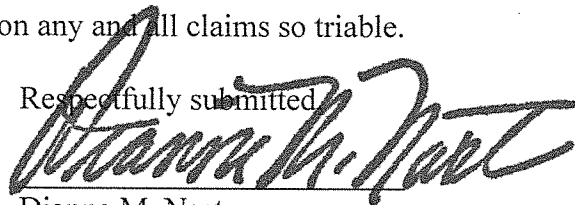
G. Such other and further relief as the Court deems just and proper.

#### **DEMAND FOR JURY TRIAL**

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: June 6, 2017

Respectfully submitted,



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